

CLAIMS:

1. In a dry assay device for determining the concentration of a first analyte in a sample of a body fluid and a second analyte in the same sample of body fluid in which the first analyte is determined colorimetrically by the color change in a first zone of a strip of absorbent material through which the body fluid sample can flow and the concentration of the second analyte is determined by an immunoassay in which the body fluid and analyte flow through a second zone of the strip which is in fluid communication with the first zone and analyte labeled specific binding partner conjugate in the body fluid is immobilized in one of these zones by interaction between the analyte or the specific binding partner and an immobilized binder in a separate zone or the strip to provide a detectable signal, the improvement which comprises placing the strip in a hollow casing constructed of a body fluid sample impervious solid material having a top and a bottom which when mated provide a hollow chamber suitable for holding the strip which chamber is in fluid communication with the exterior of the casing and when the top and bottom of the casing are mated there is formed a U shaped, fluid impervious barrier around the first discrete zone of the strip which prevents test fluid from flowing in any direction other than in the direction of the second zone and any subsequent zone(s) of the strip.

30

2. The device of Claim 1 wherein the concentration of the first analyte is clinically related to that of the second analyte.

5 3. The device of Claim 1 wherein a portion of the U shaped barrier is fixed to the top of the casing and a portion is affixed to the bottom of the casing.

10 4. The device of Claim 1 wherein the U shaped barrier extends downward along the strip beyond the end of the first discrete zone.

15 5. The device of Claim 1 wherein the second zone of the strip is divided into sub zones one of which is an absorbant wicking pad and the U shaped barrier extends downward along the strip to the end of this sub zone.

20 6. The device of Claim 1 wherein the top and bottom portion are constructed so that a press fit secures them together to form the casing having the hollow chamber.

25 7. The device of Claim 1 wherein the casing is made of plastic.

8. The device of Claim 7 wherein the plastic is polystyrene, an acrylic polymer or a polyurethane.

30 9. The device of Claim 1 wherein the bottom portion of the casing is equipped with a ridge in the shape of the strip to ensure proper placement of the strip in the casing.

10. The device of Claim 1 wherein the body fluid is urine.

11. The device of Claim 10 wherein the first analyte
5 is creatinine and the second analyte is Dpd.

12. A device for detecting the concentration of a
target analyte in a sample of body fluid relative to
the concentration of a reference analyte in the same
10 sample of body fluid which comprises:

i. a strip of absorbant material through which
the test sample can flow which strip con-
tains:

15

a) a first zone which contains reagents
for the colorimetric determination of
the reference analyte;

20

b) a second zone containing a releasable
specific binding reagent for the target
analyte which specific binding reagent
bears a detectable label and forms an
analyte/labeled specific binding part-
ner reagent upon contact with the body
25 fluid sample containing the target ana-
lyte; and

30

c) a third region which contains an immo-
bilized capture reagent for specifi-
cally binding the analyte or labeled
specific binding reagent for the ana-
lyte; and

- 05921497-030304
109080-2612260
- ii. a hollow casing having a top and bottom segment enclosing the strip of absorbent material which casing has a body fluid inlet port directly above and in visual and fluid communication with the first zone of the strip of absorbent material and one or more view ports for detecting the amount of detectable label captured in the third region wherein the hollow casing has a U shaped body fluid impervious barrier which surrounds three sides of the first region of the strip thereby allowing a sample of body fluid applied to the first region of the strip through the inlet port to flow only in the direction of the second and third regions.
13. The device of Claim 12 wherein the top and bottom segment are constructed so that a press fit secures them together to form the casing.
14. The device of Claim 12 wherein the casing is made of plastic.
15. The device of Claim 14 wherein the plastic is polystyrene, an acrylic polymer or a polyurethane.

16. The device of Claim 12 wherein a portion of the U shaped barrier is embossed from the top segment of the casing and a portion is embossed from the bottom portion so that when the top and bottom portions are mated around the strip there is formed the complete "U" shaped barrier.

17. A method for determining the concentration of a first analyte and a second analyte in a sample of body fluid which method comprises applying the sample of body fluid to the strip of Claim 12 and determining the response in the first zone and the response in the second zone.

18. The method of Claim 17 wherein the body fluid is urine.

19. The method of Claim 18 wherein the first analyte is creatinine and the second analyte is Dpd.

20. The method of Claim 17 wherein the concentration of the first analyte is clinically related to the concentration of the second analyte and the second analyte's observed concentration is corrected based on the observed concentration of the first analyte.

21. The method of Claim 20 wherein the body fluid is urine, the first analyte is creatinine and the second analyte is Dpd.